IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff	)	C.A. No. 23-975 (RGA) (SRF)
v.	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
Defendant.	)	

PLAINTIFF'S PROPOSED FINDINGS OF FACT ON INFRINGEMENT

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TRIAL WITNESSES

Citation	Witness	Witness Description
Tr. 28-41	Dr. Noah Byrd	Vice President of Global Regulatory Affairs, United Therapeutics Corp. ("UTC")
Tr. 42-45	Mr. Jason Adair (by video)	Chief Business Officer, Liquidia Technologies, Inc. ("Liquidia"), 30(b)(6) Witness
Tr. 45-46	Ms. Janet Tully (by video)	Principal Scientist, Liquidia
Tr. 47-65	Dr. Rajeev Saggar (by video)	Chief Medical Officer, Liquidia, 30(b)(6) Witness
Tr. 67-164	Dr. Steven Nathan	Expert witness called by UTC
Tr. 165-224	Dr. Richard Channick	Expert witness called by Liquidia
Tr. 228-233	Dr. Chunqin Deng (by video)	Named inventor on the '327 patent; Associate Vice President, Head of Biostatistics, Statistical Programming, and Data Management, UTC
Tr. 233-249	Dr. Peter Smith (by video)	Named inventor on the '327 patent; Senior Vice President of Product Development, UTC; 30(b)(6) Witness
Tr. 250-271, 279-302	Dr. Rajan Saggar (by video)	Fact witness; clinician at UCLA; brother of Liquidia CMO Rajeev Saggar
Tr. 303-323	Dr. Kevin Laliberte	Former Senior Vice President of Product Development and Clinical Operations, UTC
Tr. 323-363	Dr. Victor Tapson	Fact witness; clinician at Cedars-Sinai
Tr. 364-417	Dr. Aaron Waxman (by video)	Fact witness; clinician at Brigham & Women's Hospital
Tr. 418-423	Mr. Dean Bunce (by video)	Former Executive Vice President of Global Regulatory Affairs at UTC (now retired); 30(b)(6) Witness

Citation	Witness	Witness Description
Tr. 423-426	Mr. Steven Maebius (by video)	Fact witness; prosecution counsel for UTC for '327 patent
Tr. 427-431	Mr. Shaun Snader (by video)	Vice President and Associate General Counsel, Intellectual Property and Litigation, UTC
Tr. 431-553, 562-586	Dr. Richard Channick	Expert witness called by Liquidia
Tr. 586-683	Dr. Nicholas Hill	Expert witness called by Liquidia
Tr. 686-699	Dr. Peter Smith	Named inventor on the '327 patent; Senior Vice President of Product Development, UTC
Tr. 699-700	Dr. Mariana Faria-Urbina (by video)	Fact witness; former postdoctoral fellow at Brigham & Women's Hospital
Tr. 700-709	Dr. Kishan Parikh (by video)	Fact witness; clinician at WakeMed; adjunct associate professor at Duke University
Tr. 711-725	Dr. Steven Nathan	Expert witness called by UTC
Tr. 726-729	Dr. Richard Channick	Expert witness called by Liquidia
Tr. 729-758	Dr. Ronald Thisted	Expert witness called by UTC
Tr. 758-814	Dr. Bradley Wertheim	Expert witness called by UTC
Tr. 814-885, 891-931	Dr. Steven Nathan	Expert witness called by UTC

I. BACKGROUND

1. Pulmonary hypertension ("PH") is characterized by elevated blood pressure in the pulmonary artery and is diagnosed by methods including right heart catheterization. Tr. 76:13-77:5, 82:14-20, 83:11-17. PH is categorized into five groups; PH-ILD falls within WHO Group 3. Tr. 77:6-78:2; PTX-309.00006. The Court construed "pulmonary hypertension associated with interstitial lung disease" ("PH-ILD") to mean "pulmonary hypertension due, at least in part, to a patient's interstitial lung disease." D.I. 393 at 12. Interstitial lung disease ("ILD") is characterized by scarring of the lungs and is diagnosed using, *e.g.*, lung CT scans. Tr. 72:15-74:21, 81:22-82:13, 83:3-10; PTX-359.00001-02, 05-09; PTX-484.00002-03.

2. The prognosis of PH-ILD is poor, having a three-year survival of around 30%, "akin to Stage 4 lung cancer." Tr. 79:16-20. As of April 2020, no drugs were approved to treat PH-ILD. Tr. 84:11-13. PH-ILD patients typically develop ILD first and then later develop PH as a consequence. Tr. 78:18-80:2. Not every patient that has symptoms of both PH and ILD has PH-ILD; for example, patients with WHO Group 1 Pulmonary Arterial Hypertension (PAH) may have coincidental ILD that does not cause their PH. Tr. 81:4-13, 83:23-84:10; PTX-471.00001, 03-05. In April 2020, the 6th World Symposium guidelines taught doctors how to diagnose PH-ILD and distinguish it from PAH. Tr. 80:3-22, 81:14-83:22, 765:6-17; *see generally,* PTX-471; DTX-356.

3. Tyvaso and Tyvaso DPI are inhaled treprostinil products manufactured and sold by UTC. Tr. 92:7-12, 92:19-23; 174:10-13. Tyvaso is a nebulized formulation that was approved to treat PAH and PH-ILD in 2009 and 2021, respectively; it was the first drug approved for PH-ILD. Tr. 33:7-10; 92:13-18, 93:2-5. Tyvaso DPI is a dry powder formulation that was approved to treat both PAH and PH-ILD in 2022. Tr. 33:21-23, 92:19-93:1, 93:6-9, 95:13-15.

4. INCREASE is a clinical trial conducted by UTC involving Tyvaso (inhaled treprostinil administered as a nebulized solution) in patients with PH-ILD. It showed that Tyvaso

could improve exercise capacity in PH-ILD patients; these results were groundbreaking and were reported in both peer-reviewed literature and Examples 1 and 3 of the '327 patent. Tr. 91:3-8, 124:6-13, 791:10-21; JTX-1.00034-46; PTX-147; PTX-34.

5. Liquidia markets and sells Yutrepia, a dry powder formulation of inhaled treprostinil. PTX-291.00004; Tr. 93:16-19, 103:18-22, 173:7-8, 174:10-13. Tyvaso is the Reference Listed Drug ("RLD") for Yutrepia. Tr. 93:20-21. In July 2023, Liquidia amended its § 505(b)(2) NDA for Yutrepia to add a PH-ILD indication. Tr. 53:3-24, 95:7-9; PTX-291.00001. Yutrepia was approved to improve exercise ability in PAH and PH-ILD patients in May 2025. PTX-291.00004-05; Tr. 93:22-24, 95:16-18, 104:5-8, 173:9-15, 203:6-13.

6. U.S. Patent No. 11,826,327 ("'327 patent") issued on November 28, 2023, and is directed to methods of using inhaled treprostinil to improve exercise capacity in PH-ILD patients. JTX-1.00001; Tr. 71:10-18. None of the Asserted Claims use the word "measure" or require a measurement step. JTX-1.00050-51; Tr. 210:1-5. The '327 patent describes INCREASE data in the specification and is listed in the Orange Book for Tyvaso. Tr. 35:14-37:23; 124:6-13, 134:24-135:1, 135:5-8, 794:5-17, 807:18-20. Claims 5, 6, 9, and 17 are supported in the '327 patent's specification by, *inter alia*, non-limiting data from INCREASE showing that, on a population basis, the use of Tyvaso in PH-ILD patients improved exercise capacity, improved six minute walk distance ("6MWD"), improved forced vital capacity ("FVC"), reduced exacerbations of ILD, and reduced levels of NT-proBNP in blood plasma. JTX-1.00034-46; Tr. 134:24-135:1, 135:5-8, 794:13-17. UTC is the owner and sole assignee of the '327 patent. JTX-1.00001; Tr. 36:13-24.

II. INFRINGEMENT OF THE '327 PATENT

A. Liquidia represents that Yutrepia will perform equivalently to Tyvaso

7. "Liquidia intends that physicians prescribing Yutrepia should follow its label." Tr. 45:25-46:2. "Liquidia promotes the use of [Yutrepia] within the bounds of the package insert . . .

and other supporting medical information," including "[p]ublished studies of [inhaled treprostinil]." Tr. 43:16-19, 44:15-21. Thus, Liquidia instructs, encourages, recommends, and promotes infringement by doctors and patients. Tr. 113:6-18, 123:17-124:5, 125:1-4.

8. Doctors review and follow drug labels when prescribing drugs such as Tyvaso and Yutrepia to PH-ILD patients. Tr. 103:3-17, 157:15-24. "PH-ILD patients follow [their] doctors' instructions when self-administering the medication" their doctor has prescribed. Tr. 103:10-13.

9. The Yutrepia label instructs doctors and patients to prescribe and administer Yutrepia at "specific dosages with a specific device." PTX-291.00005-06, 18, 20-21; Tr. 123:17-124:5. It also says that certain Tyvaso dosages used in INCREASE are "equivalent" to specific Yutrepia doses. PTX-291.00005-06, 15; Tr. 123:23-124:5. In doing so, the Yutrepia label instructs, encourages, recommends, and promotes doctors and patients to perform each and every element of the Asserted Claims. Tr. 113:6-18, 123:17-124:5, 125:1-4.

10. Liquidia expressly relied on UTC's data from the INCREASE trial—i.e., "existing clinical efficacy and safety data for treprostinil (described in the Tyvaso PIs and peer-reviewed literature)"—when seeking FDA approval for Yutrepia in PH-ILD. PTX-377.00003; Tr. 53:3-24, 94:10-12, 96:19-99:16, 211:1-19, 214:17-217:10. FDA declared that this reliance "is acceptable." PTX-377.00003-04; Tr. 96:19-99:16. The "peer-reviewed literature" referenced by Liquidia includes the Waxman 2021 and Nathan 2021 publications. PTX-147; PTX-34.

11. The Yutrepia label relies on INCREASE to demonstrate efficacy and safety in PH-ILD patients. PTX-291.00015-17; Tr. 93:20-21, 93:25-94:5, 105:14-106:16. Liquidia has not completed any studies of Yutrepia in PH-ILD patients and had nothing to do with the conduct of INCREASE. Tr. 63:5-64:13, 94:6-12. Section 14.2 of the Yutrepia label summarizes INCREASE and states that recommended doses of Yutrepia are "equivalent" to doses of Tyvaso used in

INCREASE. PTX-291.00015-17; Tr. 52:22-53:24, 65:18-24, 105:14-107:5, 210:6-19. Liquidia thus tells doctors that Yutrepia will perform equivalently to Tyvaso in PH-ILD. Tr. 106:17-107:5, 117:17-19, 154:16-155:13, 162:23-164:7. Doctors will consult peer-reviewed publications about INCREASE to understand how Yutrepia will perform in PH-ILD patients. Tr. 157:9-24.

12. Liquidia tells doctors, patients, and payors that Yutrepia is equivalent to Tyvaso for treating PH-ILD and that Yutrepia will achieve results equivalent to Tyvaso in INCREASE. Tr. 52:22-53:24, 111:6-8, 116:7-14, 154:16-155:13, 162:23-164:7, 218:8-220:15; PTX-348.00001-05; PTX-381.00001, 06, 08, 10; PTX-382.00001; PTX-383.00001-02; PTX-384.00001-03, 08, 10-12; PTX-385.00001-02, 11, 14-17, 34, 39, 54-56; PTX-386.00001-02; PTX-387.00001, 03, 07-08, 13; PTX-388.00001-02; PTX-389.00001-02; PTX-390.00001, 04-06; PTX-391.00001-02, 39-45, 63, 65, 74-77. Liquidia's Chief Medical Officer, Dr. Rajeev Saggar, testified that Yutrepia would "meet or exceed" the performance of Tyvaso in INCREASE. Tr. 65:18-24.

13. Liquidia conducted a bioequivalence study showing that Yutrepia and Tyvaso have "comparable pharmacokinetics" and deliver equivalent amounts of treprostinil. PTX-379.00009; PTX-385.00011-12, 36-37; PTX-391.00085; Tr. 52:9-18, 53:3-14, 108:24-109:16.

14. On May 20, 2023, Liquidia invited an outside expert, Dr. Franck Rahaghi, to speak at a PH-ILD Advisory Board meeting about the INCREASE trial and its applicability to Yutrepia. Dr. Rahaghi stated that Yutrepia would "inherit" the results of the INCREASE trial along with Tyvaso's PH-ILD indication. Tr. 61:3-63:14; PTX-250.00007.

B. Liquidia had knowledge of the '327 patent and what it claims

15. Liquidia has known about the claims of the '327 patent since at least June 29, 2023, the day after the USPTO issued a notice of allowance for U.S. Patent Application No. 17/233,061. PTX-347.00002; Tr. 99:17-100:1, 100:12-101:8. On July 23, 2023, Liquidia told FDA that, as result of UTC being issued a new patent, Liquidia needed to "expedite" amending the Yutrepia

NDA to include a PH-ILD indication. PTX-242.00002; Tr. 55:10-57:9, 101:9-102:7.

16. UTC asserted the '327 patent against Liquidia on November 30, 2023. D.I. 8 at 1; JTX-1.00001. Despite its knowledge of the '327 patent, Liquidia pursued a PH-ILD indication for Yutrepia and marketed the drug for that purpose. Tr. 55:10-57:9, 101:9-102:7, 203:3-13.

C. Claims 1, 5, 6, 9, 14 and 17 are infringed

17. Liquidia stipulated to infringement of claims 1 and 14. Tr. 28:7-10, 71:1-8.

18. Liquidia knows that doctors and patients will infringe claim 5 when Yutrepia is used according to its label. Tr. 113:6-114:2, 116:7-14, 117:21-24, 123:17-125:4. In the INCREASE trial, PH-ILD patients administered inhaled treprostinil experienced a mean reduction in plasma concentration of NT-proBNP of 396.35 pg/mL at week 16 versus baseline. PTX-147.00008; Tr. 115:20-116:3, 116:7-118:5. This reduction in NT-proBNP was 1,850.30 pg/mL when compared with patients receiving placebo. PTX-147.00008; Tr. 116:7-118:5; 207:9-25. Liquidia's Yutrepia marketing materials cite to the NT-proBNP data from INCREASE. Tr. 110:1-111:8; PTX-384.00008; PTX-385.00054-55. As in INCREASE, PH-ILD patients receiving Yutrepia will likely experience a reduction in NT-proBNP of at least 200 pg/mL after 16 weeks. Tr. 116:7-117:19; 142:13-143:6, 145:5-19, 146:8-147:13.

19. Liquidia knows that doctors and patients will infringe claim 6 when Yutrepia is used according to its label. Tr. 113:6-114:2, 118:7–119:16, 123:17-125:4. In the INCREASE trial, "[s]ignificantly fewer patients in the treprostinil group than in the placebo group had exacerbations of underlying lung disease . . . P=0.02." PTX-147.00007; Tr. 118:7-119:16, 207:9-25. Liquidia's Yutrepia Provider Presentation cites these results. PTX-391.00040, 106. As in INCREASE, PH-ILD patients receiving Yutrepia will likely experience a statistically significant reduction in exacerbations of ILD. Tr. 118:7-119:16, 142:13-143:6, 145:5-19.

20. Liquidia knows that doctors and patients will infringe claim 9 when Yutrepia is used according to its label. Tr. 113:6-114:2, 119:25-121:1, 123:17-125:4. In the INCREASE trial, patients administered inhaled treprostinil experienced a statistically significant improvement in percent predicted FVC at weeks 8 and 16. PTX-147.00036; Tr. 119:25-121:1, 207:9-22. As in INCREASE, PH-ILD patients receiving Yutrepia will likely experience a statistically significant improvement in FVC after 8 or 16 weeks. Tr. 119:25-121:1, 142:13-143:6, 145:5-19.

21. Liquidia knows that doctors and patients will infringe claim 17 when Yutrepia is administered according to its label. Tr. 113:6-114:2, 121:6-123:10, 123:17-125:4. The Yutrepia label reports that, in INCREASE, patients administered inhaled treprostinil experienced a 15 m increase in 6MWD after 8 weeks. PTX-291.00015-16; PTX-147.00046; Tr. 121:13-123:2, 207:9-25. As in INCREASE, PH-ILD patients receiving Yutrepia will likely improve their 6MWD by at least 10 m after 8 weeks. Tr. 121:13-20, 142:13-143:6, 145:5-19, 153:15-154:10, 218:25-220:15.

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July 10, 2025